

R E M A R K S

Applicants have canceled claims 19 and 63 without prejudice or disclaimer of the subject matter recited therein, and applicants reserve all rights to such subject matter. Applicants have amended the specification and claims to address the informalities and indefiniteness noted by the examiner. Upon entry of this amendment, claims 44-62 will be pending.

Applicants provide a certified copy of the Austrian priority application (A 494/96). Applicants also provide copies of EP 0705 846, EP 0 416 983, and DE 3504385, along with English language abstracts from the Derwent database. The office action is discussed below.

***The claims are definite***

On pages 4-6, the examiner made several indefiniteness rejections. For definiteness, a claim need only reasonably apprise those skilled in the art of the utilization and scope of the invention. *Hybritech, Inc. v. Monoclonal Antibodies*, 231 USPQ 81, 94-95 (1986). Words are to be given their plain meaning as understood by the person of ordinary skill in the art, particularly given the limitations of the English language. See MPEP §§ 707.07(g); 2111.01 (Rev. 1, February 2003). Claims are to be given their broadest reasonable interpretation consistent with applicants' specification. See MPEP § 2111 (Rev. 1, February 2003). In sum, in order to reject the claims on definiteness grounds, it is incumbent on the examiner to show how and why

the skilled person having applicants' specification would not be apprised of the invention by the language-at-issue.

The examiner rejected claims 44 and its dependents due to the recitation of  $\text{CaCl}_2$  and a description of calcium salts on pages 19 and 20 of the specification. Claim 44 has been amended to recite "elution salts," which are useful for recovering and separating factor VIII/vWF complexes based upon molecular weight. Elution salts include soluble monovalent and divalent salts other than calcium salts. An example of an elution salt is NaCl. See page 20, lines 1-6.

The recitation of a calcium salt in claim 44 is not indefinite, however, because the claim draws a distinction between an elution salt and a calcium salt. Calcium salts are useful for separating factor VIII/vWF complex from contaminating plasma proteins when using impure protein solutions as a starting material. See the paragraph bridging pages 21-22 of the specification. Thus, according to claim 44, the contaminating plasma proteins are removed using a calcium salt, and then the Factor VIII/vWF-complex is recovered from the anion exchanger in the absence of calcium at an elution salt concentration of between  $\geq 200$  and  $< 400$  mM. Applicants therefore request withdrawal of the rejection.

Finally, applicants believe that the claim amendments to claims 56 and 57 overcome the remaining rejections.

***The claims are not anticipated by Arrighi***

On pages 6-7 of the office action, the examiner rejected claims 57-60 as anticipated by Arrighi *et al.*, EP 0 600 480. Applicants respectfully traverse this rejection.

In order to reject a claim under 35 USC § 102, the examiner must demonstrate that each and every claim limitation is contained in a single prior art reference. See *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986). Not only must the claim limitations be present, an allegedly anticipatory reference must enable the person of ordinary skill to practice the invention as claimed. Otherwise, the invention cannot be said have been already within the public's possession, which is required for anticipation. See *Akzo, N.V. v. U.S.I.T.C.*, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986); *In re Brown*, 141 USPQ 245, 249 (CCPA 1964).

Arrighi does not disclose the admixing of a purified high-molecular fraction of vWF molecules to the purified Factor VIII or Factor VIII/vWF-complex so as to provide a stable Factor VIII/vWF-complex having a molar ratio of Factor VIII to vWF of between 0.01 and 100, much less an admixing of a high-molecular fraction of vWF molecules that has a specific platelet agglutination activity of at least 50 U/mg vWF:Ag. Thus, Arrighi could not meet the limitations of the claims before, and cannot meet it now after amendment. Accordingly, applicants submit that the indefiniteness rejection should be withdrawn.

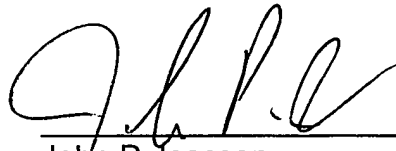
***Request***

Applicants submit that the claims are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 912-2000 should there be any questions.

Respectfully submitted,

December 23, 2003

HELLER EHRMAN WHITE & MCAULIFFE  
1666 K Street, NW, Suite 300  
Washington, D.C. 20006  
Phone: (202) 912-2000  
Fax: (202) 912-2020  
Customer No. 26633

  
\_\_\_\_\_  
John P. Isacson  
Attorney for Applicant  
Reg. No.: 33,715